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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,242	07/13/2001	Peter Eriksson	003300-798	9923

21839 7590 12/27/2002

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EXAMINER

CHEN, LIPING

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/889,242

Applicant(s)

ERIKSSON ET AL.

Examiner

Liping Chen

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

*Election/Restriction*

Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-4, 7-14 and 23, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural term cell or progenitor cell *in vitro*, wherein the substance comprises a single or double stranded, linear or circular DNA.
- II. Claims 1-3, 5, 9 and 14, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural term cell or progenitor cell *in vitro*, wherein the substance comprises a single or double stranded RNA.
- III. Claims 1-3, 6, 9, 14 and 18, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural term cell or progenitor cell *in vitro*, wherein the substance comprises a nucleic acid part and a protein part.
- IV. Claims 15 and 16, drawn to a method for identification and isolation of progenitor cells and/or stem cells comprising using the method of claim 1.

- V. Claim 17, drawn to a method for gene therapy comprising using the method of claim 1.
- VI. Claims 19 and 20, drawn to a method for propagation of neural cells comprising using the method of claim 8.
- VII. Claim 21, drawn to a method for detection of a medicinal product comprising cDNA containing expression plasmids comprising using the method of claim 1.
- VIII. Claim 22, drawn to a method for diagnostic purposes comprising using the method of claim 1.
- IX. Claims 24-26, 29-36 and 44, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural stem cell or progenitor cell *in vivo*, wherein the substance comprises a single or double stranded, linear or circular DNA.
- X. Claims 24, 25, 27, 31 and 36, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural term cell or progenitor cell *in vivo*, wherein the substance comprises a single or double stranded RNA.
- XI. Claims 24, 25, 28, 31, 36 and 40, drawn to a method for introducing a substance comprising a nucleic acid into a mammalian neural term cell or progenitor cell *in vivo*, wherein the substance comprises a nucleic acid part and a protein part.

- XII. Claims 37 and 38, drawn to a method for identification and isolation of progenitor cells and/or stem cells comprising using the method of claim 24.
- XIII. Claims 39 and 45, drawn to a method for treatment of neurological insult, disease, deficit or condition comprising using the method of claim 24.
- XIV. Claim 41, drawn to a method for propagation of neural cells comprising using the method of claim 30.
- XV. Claim 42, drawn to a method for detection of a medicinal product comprising cDNA containing expression plasmids comprising using the method of claim 24.
- XVI. Claim 43, drawn to a method for diagnostic purposes comprising using the method of claim 24.

Note: 1) Claim 20 is grouped as it depends on claim 19, as claim 18 does not contain propagated neural cells.

2) Claim 36 is grouped as it depends on claim 24, as claim 1 is *in vitro* method, claim 36 recites a cell in the central nervous system of a patient, it meets *in vivo* condition.

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This application Groups I and IX contain claims directed to more than one invention. The inventions distinguished by different nucleic acids encoding different proteins.

These proteins are: protein that activate proliferation, or differentiation, or lineage determination; or fluorescent protein, or radioactively tagged nucleic acid.

These are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. They are different inventions because they have different chemical structures, physical properties and biological functions, require different technique feature for detection.

Applicant is required to select one invention from an elected group for examination.

Group XVI contains claims directed to more than one invention. The inventions distinguished by different diseases or conditions.

The diseases or conditions are: neurological insult, deficit, or a specific condition or a specific disease.

These are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. They are different inventions because each disease has different causes and requires different

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treatment. Applicant is required to select one invention from an elected group for examination.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I encompasses a method for introducing a substance comprising a nucleic acid into a mammalian neural stem cell or progenitor cell *in vitro*, wherein the substance comprises a single or double stranded, linear or circular DNA. Groups II-XVI are directed to different methods that require different special technical features to accomplish. Groups II-VIII are directed to a method *in vitro*, Groups IX-XVI are directed to methods *in vivo*. Groups II and III contain different substance: RNA or DNA+protein, each requires different carrier for delivery or specific detection technique; Although Groups IV-VIII require the method of group I, however, a specific technique feature is required to accomplish the method of each group. The reasoning for Groups IX-XVI is the same as the reasoning for Groups I-VIII. Moreover, The methods of introducing a substance comprising a nucleic acid into a mammalian neural stem cell were well-known in the art, as evidenced by Anderson et al. (US Patent No. 6,001,654, issued 12/14/1999). Thus, Groups I-XVI lack a common special technical feature. Further, 37 CFR 1.475 does not provide for multiple independent products, methods of manufacture and methods of use (37

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CFR 1.475(d). Therefore, The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Dianiece Jacobs, Patent Analyst, at (703) 305-3388. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Liping Chen, Ph.D.  
Patent Examiner  
Group 1632

**PETER PARAS**  
**PATENT EXAMINER**

